

CLAIMS

1. Method for distracting in a given direction two tissue surfaces, comprising consecutively inserting between the tissue surfaces a plurality of wafers to create a column of wafers, the column being oriented between the tissue surfaces so as to expand in the given direction as wafers are consecutively added to the column.
2. The method of claim 1 further including the step of creating a second column of wafers oriented between the two tissue surfaces separate from the first column of wafers.
3. The method of claim 1 further including the step of consecutively inserting between the tissue surfaces a plurality of wafers to create another column of wafers, the column being oriented between the tissue surfaces so as to expand in a direction opposite the given direction as wafers are consecutively added to the column.
4. The method of claim 1 including the step of inserting between the tissue surfaces an elongated guide track along which the wafers travel during insertion.
5. The method of claim 4 including the step of inserting each wafer or stack of wafers subsequent to the first wafer or stack of wafers between the next preceding wafer and a base.
6. The method of claim 5 wherein the base is the guide track.
7. The method of claim 5 wherein the base is a wafer adjacent the next preceding wafer.
8. The method of claim 5 wherein the wafers have leading and trailing beveled ends, the method comprising the step of engaging the leading beveled end of one wafer with the trailing beveled end of the next preceding wafer to enable the one wafer to be inserted between the guide track and the next preceding wafer to thereby urge the preceding wafer away from the guide track in the given direction.
9. The method of claim 5 including the step of urging the trailing edge of a first wafer away from the track to enable another wafer to be inserted between the base and the first wafer.
10. The method of claim 8 or claim 9 including the step of restraining an inserted wafer from movement during insertion of a next following wafer along the track between the base and the inserted wafer.
11. The method of claim 8 or claim 9 wherein the guide track includes an end portion upon which the wafers are stacked between the tissue surfaces, the method comprising the step of uncoupling the end portion and removing the remainder of the guide track from between the tissue surfaces while allowing the end portion to remain with the wafer column.
12. The method of claim 6 including the step of lifting the first wafer with the guide track to allow the next preceding wafer to be inserted between the track and the first wafer.

13. The method of claim 1 including the step of providing a hardenable, fluent bone filler between the tissue surfaces about and in contact with the wafer column.
14. The method of claim 13 wherein one or more of the wafers have filler-receiving orifices, the method including the step of providing the fluent bone filler in the orifices.
15. The method of claim 13 wherein the wafers are so configured as to provide channels, grooves, or holes through and on the surface of each wafer when they are stacked, the method including the step of providing the fluent bone filler within the channels.
16. The method of claim 15 wherein the wafer column includes orifices communicating the channels with each other, the method comprising the step of providing the fluent bone filler within the channels and orifices.
17. The method of claim 14 including the step of providing a membrane around the wafer column to control flow of the fluent bone filler into surrounding cancellous bone.
18. The method of claim 14 including the step of providing a membrane around the wafer column to control flow of the fluent bone filler on and into the wafer column.
19. The method of claim 4 wherein the elongated guide track is curved generally in a plane normal to the given direction, the method comprising the step of consecutively inserting wafers curved so as to follow the track to provide a curved wafer column.
20. The method of claim 4 wherein the plurality of wafers are interconnected with a flexible tether.
21. The method of claim 20 including the step of removing the wafer column by removing the last inserted wafer and using the connecting member to remove the earlier inserted wafers.
22. The method of claim 20 wherein the tether is positioned along the wafers to provide a continuous sliding surface to facilitate removal of the column of wafers.
23. The method of claim 20 wherein the wafers and the flexible tether are integrally formed.
24. The method of claim 4 wherein the tissue surfaces are part of a single bone, the method including the step of forming an orifice within the bone and between the tissue surfaces configured to enable insertion of the guide track.
25. The method of claim 4 wherein the tissue surfaces are opposing surfaces of two bones, the method including the step of forming an orifice between the opposing surfaces of the two bones configured to enable insertion of the guide track.
26. The method of claim 4 including the step of inserting between the tissue surfaces an elongated access channel within which is received the guide track to afford access of the track between the tissue surfaces.

27. The method of claim 26 wherein the access channel has collapsed and expandable configurations, the method including the steps of inserting the access channel in its collapsed configuration between the tissue surfaces and then expanding the access channel between the tissue surfaces laterally of its length and in a direction generally normal to the given direction to enable the access channel to receive the guide track.
28. The method of claim 1 wherein adjacent wafers include a flexible tether extending between them, the method including the step of withdrawing one wafer from between the tissue surfaces by withdrawing an adjacent wafer.
29. The method of claim 1 including the step of applying a liquid to the wafers.
30. The method of claim 29 wherein the liquid is a solvent carried in micro spheres to enhance bonding wherein the micro spheres are ruptured during insertion of the wafer.
31. The method of claim 1 including the step of applying a hardenable fluent designed for time-delayed activation.
32. The method of claim of claim 30 wherein the micro spheres further include an osteoinductive agent.
33. The method of any one of claims 1-32 wherein the wafers are curved in a plane generally normal to the given direction.
34. The method of claim 1 wherein one or more wafers are of non-uniform thickness.
35. The method of claim 34 wherein each wafer has a length and a width and wherein one or more wafers increases in thickness along the wafer length.
36. The method of claim 34 wherein each wafer has a length and a width and wherein one or more wafers increases in thickness along the wafer width.
37. The method of any one of claims 1 – 9 and 13 – 24, 26 - 36, wherein the tissue surfaces are superior and inferior portions of a fractured vertebral body, the method including the step of inserting consecutive wafers into the body of the vertebra between the superior and inferior portions to distract the portions generally in the direction of the vertebral axis until the normal height of the vertebra is substantially attained.
38. The method of claim 1 further including the steps of consecutively inserting between the tissue surfaces a second plurality of wafers at a second position to create a second column of wafers, the column being oriented between the tissue surfaces so as to expand in the given direction as wafers are consecutively added to the column.
39. Apparatus for the distraction of tissue surfaces in a given direction, comprising a plurality of wafers stackable consecutively one upon another to form a column extending in the given direction, the

wafers having top and bottom surfaces enabling them to move with respect to one another in a second direction generally normal to the given direction as a wafer column is formed, and the wafers having opposed leading and trailing ends so cooperatively beveled as to force the top surface of one wafer to engage and ride beneath the bottom surface of another wafer when the leading edge of one wafer is urged in the second direction against the trailing edge of another wafer.

40. The apparatus of claim 39 wherein the engaging wafer surfaces are provided with complementary configurations restraining the wafers from slipping out of the column.

41. The apparatus of claim 40 wherein the complementary configurations are complementary ridges and grooves.

42. The apparatus of claim 40 wherein the complementary ridges and grooves have dovetail ridge and groove configurations.

43. The apparatus of claim 40 wherein the complementary configurations are configured to enable the wafers to rotate in a plane normal to the given direction while remaining in the column.

44. The apparatus of claim 40 wherein the complementary configurations comprise detent configurations so configured as to restrain any lateral movement between adjacent wafers in a column.

45. The apparatus of claim 40 wherein the complimentary configurations comprise a cylindrical indent.

46. The apparatus of claim 40 wherein the complimentary configurations comprise a spherical indent.

47. The apparatus of claim 40 wherein the wafers have top and bottom surfaces so configured as to permit limited rotation of one wafer with respect to another wafer about an axis parallel to the second direction.

48. The apparatus of claim 40 wherein the wafers comprise a dovetail and a cylindrical indent to constrain all degrees of freedom.

49. The apparatus of claim 39 wherein the wafers have cylindrical interfaces to provide axial translation along the axis of the cylinder and rotational movement about the radius of the cylinder.

50. The apparatus of claim 39 wherein the wafers have spherical interfaces.

51. The apparatus of claim 39 further including a pin for locking the wafers in place.

52. The apparatus of claim 40 wherein the wafers have a top surface and a bottom surface, the bottom surface having a leading edge, a trailing edge, and two lateral edges, the wafer further including a lip formed along the bottom surface for limiting axial travel of a subsequent wafer.

53. The apparatus of claim 52 wherein the lip extends along all edges of the bottom surface except for the trailing edge.

54. The apparatus of claim 52 wherein the lip extends along the leading edge of the bottom surface.
55. The apparatus of claim 52 wherein the lip extends along the lateral edges of the bottom surface.
56. The apparatus of claim 39 wherein the wafers are marked with a radio-opaque material for observation under fluoroscopy.
57. The apparatus of claim 39 including a flexible tether extending between consecutive wafers to facilitate withdrawal of wafers from between the tissue surfaces.
58. The apparatus of claim 57 wherein the wafers have an upper surface and a bottom surface and the tether extends along the upper surface of the wafers.
59. The apparatus of claim 57 in which the tether extends between the leading edge of one wafer and the trailing edge of the preceding wafer.
60. The apparatus of claim 57 in which the tether extends between the trailing edge of one wafer and the trailing edge of the preceding wafer.
61. The apparatus of claim 59 in which the tether is in the form of a web which, when the wafers are stacked, extends between adjacent wafers.
62. The apparatus of any one of claims 39 – 61 wherein the wafers are curved in a plane generally normal to the given direction.
63. The apparatus of claim 39 wherein one or more wafers are of non-uniform thickness.
64. The apparatus of claim 63 wherein each wafer has a length and a width and wherein one or more wafers increases in thickness along the wafer length such that the one or more wafers are configured as a wedge.
65. The apparatus of claim 63 wherein each wafer has a length and a width and wherein one or more wafers increases in thickness along the wafer width such that the one or more wafers are configured as a wedge.
66. The apparatus of claim 39 where the wafers have a surface and further including a liquid on the surface of the wafers.
67. The apparatus of claim 66 wherein the liquid is a solvent to enhance bonding.
68. The apparatus of claim 67 wherein the solvent is designed for time-delayed activation.
69. The apparatus of claim 39 wherein the wafers have a surface and further including a solvent carried in micro spheres on the surface of the wafers to enhance bonding.
70. The apparatus of claim 69 wherein the micro spheres further include an osteoinductive agent.
71. The apparatus of claim 70 wherein the osteoinductive agents are designed for time release.

72. Apparatus for the distraction of tissue surfaces in a given direction, comprising a guide track having an end portion insertable between the tissue surfaces, and a plurality of wafers configured to travel consecutively along the track to the end portion, the wafers and track being so configured as to form upon the end portion a stacked column extending in the given direction to distract the tissue surfaces.

73. The apparatus of claim 72 wherein the guide track is configured at its end portion to form a second stacked column of wafers extending in a direction opposite the given direction to distract the tissue surfaces.

74. The apparatus of claim 72 wherein the wafers have leading and trailing ends so configured as to enable each wafer after the first to slide between the guide track and the next preceding wafer.

75. The apparatus of claim 72 wherein the wafers have leading and trailing ends so configured as to enable each wafer after the first two wafers to slide between two previously inserted wafers.

76. The apparatus of claim 72 wherein the track is configured for positioning along the wafer column and insertion of a wafer between two wafers in the column.

77. The apparatus of claim 72 wherein the wafers have beveled leading and trailing ends such that each wafer after the first to slides between the guide track and the next preceding wafer.

78. The apparatus of claim 72 including an elongated access channel within which is received the guide track to afford access of the track between the tissue surfaces, and a plunger slidable along the track and configured to engage the trailing end of a wafer and urge the leading end of the wafer distally.

79. The apparatus of claim 78 wherein the access channel has collapsed and expandable configurations.

80. The apparatus of claim 66 including a magazine containing the wafers and positioned to supply the wafers to the track distally of the plunger.

81. The apparatus of claim 66 wherein the wafers have top and bottom surfaces and are stacked in the magazine with a top surface of one wafer supporting the bottom surface of an adjacent wafer.

82. The apparatus of claim 80 wherein the wafers are aligned in the track with the leading edge of one wafer adjacent the trailing edge of a preceding wafer.

83. The apparatus of claim 72 wherein the track is configured to restrain each wafer from further movement after the wafer is inserted and during insertion of subsequent wafers.

84. The apparatus of claim 83 wherein the track has a distal edge and the wafers are restrained from further travel along the track by an upper lip of the track at its distal edge.

85. The apparatus of claim 84 wherein the distal edge is movable for withdrawal of the track from the wafer column.

86. The apparatus of claim 84 wherein the distal edge is releasable for withdrawal of the track from the wafer column.
87. The apparatus of claim 72 wherein the wafers are configured to provide channels, grooves, or holes through and on the surface of each wafer for receiving fluent bone filler.
88. The apparatus of claim 72 further including a membrane around the wafer column to control flow of the fluent bone filler into surrounding cancellous bone.
89. The apparatus of claim 72 further including a force transducer for measuring the force exerted by a wafer inserted into the column on the column.
90. The apparatus of claim 89 further including a display for displaying the measured force.
91. The apparatus of claim 89 further including an adjustable force guideline for column distraction force.
92. The apparatus of claim 72 further including a force transducer for measuring the force exerted by the column on the tissue surfaces.
93. The apparatus of claim 92 further including a display for displaying the measured force.
94. The apparatus of claim 72 further including a counter for monitoring the number of wafers inserted into the column.
95. The apparatus of claim 94 further including a display for displaying the number of wafers.
96. Kit for the distraction of tissue surfaces in a given direction, comprising:
a plurality of insertable wafers;
a guide for forming a body access;
a channel for expanding the body access;
an inserter for inserting the wafers into the channel;
a bone filler injection channel; and
a sterile packaged tray containing the wafers, the guide, the channel, the inserter, and the bone filler injection channel.
97. The kit of claim 96 further including bone filler.

Clean Version of the New Claims

Please add the following as new claims 98-173:

98. A method of treating tibial plateau compression fractures, comprising the steps of:
accessing the space under the tibial plateau in a tibia between two generally opposed surfaces of the fractured tibia; and
consecutively introducing a plurality of elements in contact with each other between the opposed surfaces to distract and support such surfaces to reduce the fracture and support the tibial plateau.
99. The method of claim 98, wherein said elements are introduced in contact with each other generally in the direction of the axis of the tibia.
100. The method of claim 98 wherein said elements are introduced by moving at least one element to a different position upon introduction of a subsequent element.
101. The method of claim 100 wherein said at least one element is moved by contacting a surface thereof with a surface of said subsequent element.
102. The method of claim 101 wherein the accessing step includes the step of placing an elongated access channel in communication with the space between said opposing surfaces and introducing the elements through said channel.
103. The method of claim 102, further including the step of providing a bone filler in contact with the elements.
104. The method of claim 101 wherein said elements are wafers, said wafers being introduced between said opposing surfaces by stacking one wafer atop another wafer.
105. The method of claim 98, further including the step of providing an outer member and introducing said elements into said member.
106. The method of claim 98, wherein said elements have arcuate contact surfaces.

107. The method of claim 98, wherein said elements have generally flat contact surfaces.
108. A method of treating tibial plateau compression fractures, comprising the steps of:
 - accessing the space under the tibial plateau on a tibia between two generally opposed surfaces of the fractured tibia; and
 - stacking a plurality of wafers in the tibia in the general direction of the axis of the tibia between the opposed surfaces to distract and support such surfaces to reduce the fracture and support the tibial plateau.
109. The method of claim 108, wherein said wafers are stacked by consecutively inserting said wafers one atop the other to form a column extending in the direction of the axis of the tibia.
110. The method of claim 109, wherein said wafers are consecutively inserted in a direction substantially normal to the axis of the tibia.
111. The method of claim 110, wherein said wafers are consecutively inserted by slidably moving one wafer along a surface of another wafer.
112. The method of claim 111, including the step of inserting between the opposing surfaces under the tibial plateau an elongated guide track along which the wafers travel during insertion.
113. The method of claim 112, including the step of inserting each wafer subsequent to the first wafer between the next preceding wafer and a base.
114. The method of claim 113, wherein the base is the guide track.
115. The method of claim 113, wherein the base is a wafer adjacent the next preceding wafer.
116. The method of claim 113, wherein the wafers have leading and trailing beveled ends, the method comprising the step of engaging the leading beveled end of one wafer with the trailing beveled end of the next preceding wafer to enable the one wafer to be inserted

between the guide track and the next preceding wafer to thereby urge the preceding wafer away from the guide track in the direction of the axis of the tibia.

117. The method of claim 109, including the step of providing the fluent bone filler in an access path to the tibial plateau and in contact with the wafer column.
118. The method of claim 117, wherein the access path is an opening through a tibial lateral wall, the method including the step of providing the filler in the lateral wall opening.
119. The method of claim 109, wherein the accessing step includes the step of inserting under the tibial plateau an elongated access channel through which said wafers are inserted.
120. The method of claim 112, wherein the accessing step includes the step of inserting under the tibial plateau an elongated access channel having collapsible and expandable configurations, the method including the steps of inserting the access channel in its collapsed configuration under the tibial plateau and then expanding the access channel between the opposing surfaces laterally of its length and in a direction generally normal to the direction of the axis of the tibia to enable the access channel to receive the guide track therewithin.
121. The method of claim 108 including the step of applying a liquid to the wafers.
122. The method of claim 121, wherein the liquid is a solvent carried in micro spheres to enhance bonding wherein the micro spheres are ruptured during insertion of the wafer.
123. The method of claim 122, wherein the micro spheres further include and osteoinductive agent.
124. The method of claim 108 including the step of applying a hardenable fluent material designed for time-delayed activation.
125. The method of claim 108, wherein said wafers are non-removably maintained in the tibia.

126. An apparatus for the reduction and stabilization of tibial plateau compression fractures, comprising a plurality of elements in cooperative contact forming a structure between said opposing surfaces under the tibial plateau generally extending in the direction of the axis of the tibia, said structure being formed by the consecutive receipt of said elements between said opposing surfaces.
127. The apparatus of claim 126, wherein each element has an interface, the interfaces of elements in contact being configured to provide said cooperative contact.
128. The apparatus of claim 127, wherein said interfaces are configured to provide unconstrained degrees of cooperative contact.
129. The apparatus of claim 127, wherein said interfaces are configured to provide semi-constrained selective degrees of cooperative contact.
130. The apparatus of claim 127, wherein said interfaces are configured to provide constrained degrees of cooperative contact.
131. The apparatus of claim 127, wherein said interfaces are arcuate.
132. The apparatus of claim 131, wherein said arcuate surfaces are generally cylindrical.
133. The apparatus of claim 131, wherein said arcuate surfaces are generally spherical.
134. The apparatus of claim 127, wherein said interfaces are generally flat.
135. The apparatus of claim 134, wherein said structure is defined by a plurality of wafers each having said generally flat interfaces, one wafer being disposed atop another wafer to form said structure.
136. An apparatus for the reduction and stabilization of tibial plateau compression fractures comprising a plurality of stackable wafers cooperatively forming a column generally in the direction of the axis of the tibia between said two opposing surfaces under the tibial

plateau, the wafers each having a contact surface, a contact surface of one wafer being slidably receivable on a contact surface of another wafer in a sliding direction generally normal to the axis of the tibia.

137. The apparatus according to claim 136, wherein a stackable wafer comprises a single wafer.
138. The apparatus according to claim 136, wherein a stackable wafer comprises multiple wafers.
139. The apparatus of claim 136, wherein one or more wafers are curved in a plane generally normal to the direction of the axis of the column.
140. The apparatus of claim 136, wherein one or more wafers are of non-uniform thickness.
141. The apparatus of claim 136, wherein each wafer has a length and a width and wherein one or more wafers increases in thickness along the wafer length such that the one or more wafers are configured as a wedge.
142. The apparatus of claim 136, wherein the wafer contact surfaces are provided with complementary configurations to restrain the wafers from slipping out of the column.
143. The apparatus of claim 142, wherein the complementary configurations are complementary ridges and grooves.
144. The apparatus of claim 143, wherein the complementary ridges and grooves have dovetail ridge and groove configurations.
145. The apparatus of claim 142, wherein the complementary configurations are configured to enable the wafers to rotate in a plane normal to the given direction while remaining in the column.

146. The apparatus of claim 142, wherein the complementary configurations comprise detent configurations so configured as to restrain any lateral movement between adjacent wafers in a column.
147. The apparatus of claim 142, wherein the complementary configurations comprise a cylindrical indent.
148. The apparatus of claim 142, wherein the complementary configurations comprise a spherical indent.
149. The apparatus of claim 142, wherein the wafer contact surfaces are configured to permit limited rotation of one wafer with respect to another wafer about an axis parallel to the sliding direction.
150. The apparatus of claim 136, wherein the wafers comprise a dovetail and a cylindrical indent to constrain all degrees of freedom.
151. The apparatus of claim 136, wherein the wafer contact surfaces have cylindrical interfaces to provide axial translation along the axis of the cylinder and rotational movement about the radius of the cylinder.
152. The apparatus of claim 136, wherein the wafers have spherical interfaces.
153. The apparatus of claim 136, further including a pin for locking the wafers in place.
154. The apparatus of claim 136, wherein each wafer has a leading edge, a trailing edge, and two lateral edges, the wafer further including a lip formed along a bottom surface for limiting axial travel of a subsequent wafer.
155. The apparatus of claim 154, wherein the lip extends along all edges of the bottom surface except for the trailing edge.

156. The apparatus of claim 154, wherein the lip extends along the leading edge of the bottom surface.
157. The apparatus of claim 154, wherein the lip extends along the lateral edges of the bottom surface.
158. The apparatus of claim 136, wherein the wafers are marked with a radio-opaque material for observation under fluoroscopy.
159. The apparatus of claim 136 wherein each wafer has a length and a width and wherein the wafer defining the bottom wafer in said column has a length larger than at least one other wafer in said column.
160. The apparatus of claim 136 wherein each wafer has a length and a width and wherein the wafer defining the top wafer in said column has a length larger than at least one other wafer in said column.
161. The apparatus of claim 160 wherein said wafer defining said bottom wafer in said column has a length larger than at least one other wafer in said column.
162. The apparatus of claim 136 wherein said wafers comprise implant materials.
163. The apparatus of claim 162, wherein one or more wafers have at least one orifice for receiving a filler material therein.
164. The apparatus of claim 162, wherein said wafers further comprise osteoinductive agents.
165. The apparatus of claim 162, wherein said wafers further comprise a drug therapy.
166. The apparatus of claim 136 further including an outer member covering at least a portion of such wafer column.
167. The apparatus of claim 166, wherein said outer member is permeable.

168. The apparatus of claim 167, wherein said outer permeable member comprises a material of macro-porosity.
169. A kit for the treatment of tibial plateau compression fractures, comprising;
a plurality of wafer stacks of various thicknesses adapted to form a column between opposing surfaces under the tibial plateau of a tibia; and
a wafer inserter for inserting said plurality of wafer stacks between said opposing surfaces, said wafer inserter being adapted to selectively insert consecutive wafer stacks of the same or different thicknesses between said opposing surfaces of the tibia to thereby form said column of wafers under the tibial plateau.
170. The kit of claim 169, wherein at least a number of said plurality of wafer stacks include only one wafer.
171. The kit of claim 169, wherein at least a number of said plurality of wafer stacks include more than one wafer.
172. A kit for the treatment of tibial plateau compression fractures, comprising;
a plurality of elements adapted for contact with each other; and
an inserter for consecutively inserting said plurality of elements between opposing surfaces in a tibia in a manner such that such elements are placed in contact with each other in a direction generally extending along the axis of the tibia.
173. The kit of claim 172 further including bone filler.